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Diabetes-Related Foot Care Interventions for Preventing Diabetic Foot Ulcerations: A Systematic Review of Literature

David Oni*

Oregon Health and Science University, School of Nursing, USA

***Corresponding author:** David Oni, Oregon Health and Science University, School of Nursing, 1 University Blvd, La Grande OR, USA, Tel: (509)919-9798; E-mail: onid@ohsu.edu

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Abstract

Background: Foot care practices are strongly recommended as part of preventive strategies for diabetes foot ulcers (DFUs). However, preventing DFUs, and re-ulceration, in patients with diabetes remains very challenging despite the preventive foot care recommendations. There is insufficient evidence of benefits supporting the effectiveness of self-foot care practices in preventing DFUs and re-ulceration patients with diabetes mellitus. The purpose of this study is to critically appraise the current interventional research studies focused on foot care practices in patients with diabetes to establish the relationship between self-foot care practices and DFUs reduction, clearly pinpoint the current gaps in research, and provide supports for designing future interventional research studies, so that stronger recommendations can be provided for primary and secondary prevention of DFUs in clinical practice.

Methods: PubMed, CINAHL, Psych-info, and Cochrane reviews databases were searched. Only RCTs, and systematic reviews studies that evaluated foot care interventions for preventing DFUs and re-ulceration in people with diabetes mellitus were included. Findings were reported according to the "Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA). Primary outcomes were foot care practices, foot ulcers, re-ulceration, and foot amputations.

Results: Nine systematic reviews and 4 RCTs were finally included. Most included studies demonstrated only short-term effects on foot care practices and little benefits in preventing DFUs, re-ulceration and lower extremity amputations.

Conclusions: There is a paucity of high-quality evidence, and an urgent need for well-designed RCTs to provide robust evidence on interventions for prevention of DFUs and provide stronger recommendations for health care practitioners.

Keywords: Diabetes mellitus; Diabetic foot ulcers; Diabetic foot care practices; Interventions; Systematic reviews; Randomized controlled trials

Abbreviations: DFUs-Diabetic Foot Ulcers; ADA-America Diabetes Association; DM-Diabetes Mellitus; RCTs-Randomized Controlled Trials; IDF-International Diabetic Federation

Introduction

Diabetic foot ulcers (DFUs) are one of the most significant and devastating complications of diabetes mellitus [1]. It is estimated that as many as 25 percent of diabetes patients will develop at least one foot ulcer in their lifetime [2,3]. Despite medical treatment and patient-directed foot care interventions, most DFU resulted in high levels of mortality and morbidity such as re-ulceration, lower extremity amputations, impaired quality of life, severe pain, prolonged hospitalization, and financial burden [2-4].

DFU is defined as a full thickness wound below the ankle in a person with diabetes, irrespective of duration [5]. DFUs may be divided into two groups: neuropathic ulcers and neuro-ischemic ulcers, with the crucial difference between them being the absence or presence of ischemia. Most DFUs are preceded by neuropathy. Peripheral neuropathy is the most important causal pathway leading to foot ulceration and often leads to sensory deficit with the loss of protective pain sensation. Ischemia, on the other hand, results from atherosclerotic peripheral vascular disease, which usually affects the distal vessels of the lower limb [6]. Re-ulceration and infection can complicate any type of DFU making it one of the most common causes of hospital admission among people with diabetes [7,8].

Preventive foot care practices are strongly recommended as part of preventive strategies for DFUs, and re-ulcerations in diabetes patients

with or without DFUs [9-11]. The current clinical standard of care for preventive foot care practices includes: annual comprehensive foot care assessment to identify risk factors for DFU, re-ulceration and amputation, foot care inspection by trained healthcare practitioners on every clinical visit, preventive foot care education, specialized therapeutic foot wears and referral to podiatrists for on-going preventive care and life-long surveillance [11-13]. Preventive foot care education are directed to promote self-foot care practices such as daily foot inspection, toe and nail care, and foot hygiene (daily washing of feet, and avoiding walking bare-footed), and to preventing DFU, or re-ulceration of a DFU, and promoting foot health [11].

Despite these preventive interventions, patients continue to develop DFUs. There is no robust evidence that the current preventive clinical practice is sufficient in promoting self-foot care practices and preventing DFUs [10,12-14]. This makes primary prevention of DFUs and re-ulceration challenging. It is therefore imperative to review current evidence on foot care practices intervention to establish gaps in literature, and inform future research studies so that stronger recommendations can be provided for future clinical practice.

This systematic review of literature will establish the relationship between self-foot care practices and DFUs reduction, clearly pinpoint the current gaps in research, and provide supports for designing future interventional research studies, so that stronger recommendations can be provided for primary and secondary prevention of DFUs in clinical practice.

Methods

This systematic review was reported according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) [14]. Detailed steps of how randomized controlled trials, and systematic reviews were searched, reviewed and retained are represented with PRISMA flow chart (Figure 1). The population of interest for this study was adults with type 1 or type 2 diabetes mellitus, with or without DFUs, who participated in preventive foot care intervention research studies, aimed at improving foot care practices, preventing DFUs and re-ulceration. The primary outcomes of interest were DFUs, recurrent DFUs, amputations, diabetic foot self-care practices. The secondary outcomes were diabetes foot care knowledge, foot care behaviors, callus development and hospital admissions. Only randomized control trials (RCTs), and systematic reviews aimed at preventing DFUs, re-ulceration, and amputations in the population of interest were included. The author excluded studies which did not address foot care in patients with diabetes and studies focused on acute or chronic wounds resulting from surgical procedures in patients with diabetes. Only foot care intervention studies on patient with or without active DFUs, including those reporting patients with recurrent DFUs and amputations were reported. The author also reported interventions with proxy outcomes related to DFU preventions such as foot care knowledge, and foot care practices and behaviors. Non-randomized control trials, cohort studies, case-control studies, and cross-sectional studies were excluded.

The US Library of Medicine (PubMed) was searched using the medical subject subheading (MeSH) terms to specify search parameters (diabetes mellitus and diabetic foot ulcers and foot care or foot care, and randomized controlled trial or systematic reviews). Cochrane Online Library (Cochrane), Psychological Information Database (Psych-INFO), Cumulative Index Nursing and Allied Health Library (CINAHL), and Google Scholars were searched with the same searching parameters diabetes foot care is a focus of the study across health fields such as nursing, medicine, and podiatry. The authors assessed and identify abstracts of studies found in relation to the scope and the goal of this review. The literature search was conducted on 20th of November 2016, covered publications in English Language only; from 2001-2016; not restricted to a geographical location. The searching parameters were prepared with the help of a clinical librarian.

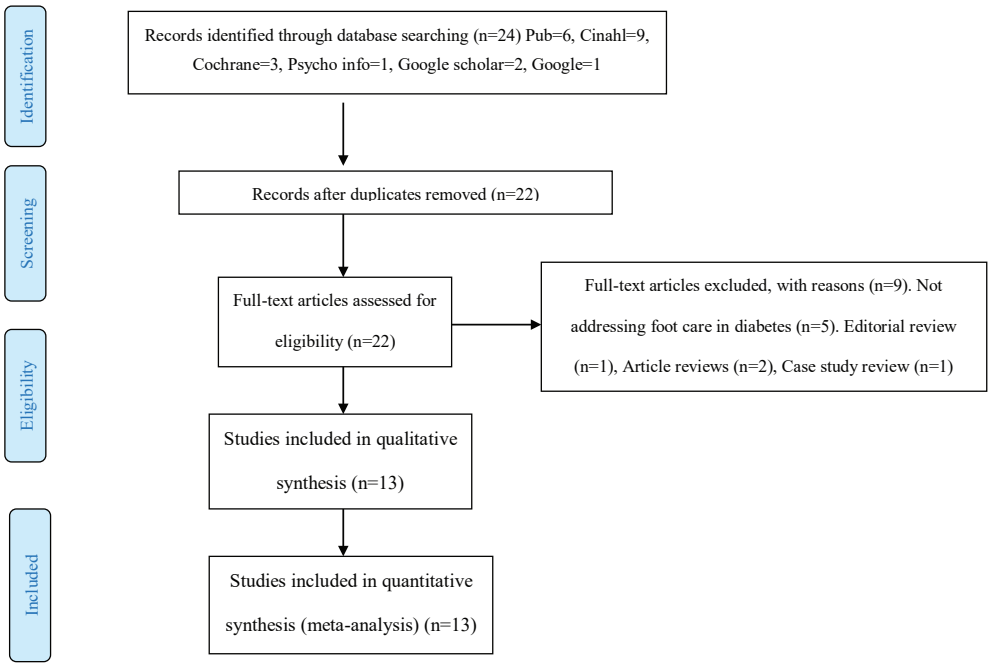

Figure 1: Quantitative Review Flow Chart Diagram.
Moher D, et al. (2009) [15].

Table 1: Cochrane Collaborative Tool: Review author judgment of each methodological quality for each included RCTs study.

Authors	Random Sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (Detection bias)	Incomplete outcome data (attrition bias)	Selective Reporting (Reporting bias)	Other biases
Lavery, et al. [18]	+	-	+	+	+	-
Liang, et al. [9]	+	-	-	+	-	-
Corbett CF [18]	+	-	-	+	+	-
Lincoln NB, et al. [19]	+	+	+	+	+	+

Selection of studies

A total of nineteen (n=19) published articles were initially found from PubMed, CINAHL, Cochrane, and Psychinfo, and five (n=5) from other records (Google Scholar). The abstracts of the twenty-four articles were reviewed and four papers (n=4) were excluded for sameness. A full text of one paper was unavailable for review despite several for a full text review of the article. A full text review of the nineteen (n=19) published papers was completed. Six studies were excluded for the following reasons: Two published papers (n=2) excluded for not address foot care in diabetes; One article was excluded for being an editorial review, two papers excluded for being article reviews, and additional one paper was excluded because it was a case study review (Figure 1). Thirteen peer-reviewed publish articles were finally included for qualitative analysis, of which 9 were systematic reviews, and 4 were randomized controlled trials.

The title and abstract of each article was initially reviewed and assessed on meeting criteria for inclusion to review the full text publication. The researcher also evaluated the included RCTs for methodological quality (i.e., risk of bias), using Cochrane Collaboration tool16, was used by the researcher to examine the included RCTs. The tool addresses: randomization, allocation concealment, blinding, whether outcome data is complete and selective outcome reporting. Details of how Cochrane Collaboration tool was used to assess risks of bias from each RCTs articles reviewed is represented with Cochrane collaborative tool table [15-17] (Table 1). Risk of bias was scored for each study as >4 plus (+) (lower risk of bias), to two or more minuses (-), (higher risk of bias). Relevant data from included studies were extracted and summarize in the table of which included: the sample size and characteristics, sampling technique and settings, the primary and secondary outcomes, findings and implication of each study (the supplementary material). The author reached consensus and provide recommendations for future interventions based on the strength of the available evidence.

Results

The quantitative literature review examined whether foot care interventions impact self-foot care practices and prevent foot ulceration in patients with type 1 or type 2 diabetes. The narrative summary of the results of included studies are summarized and reported in the table of findings (Table 2).

Diabetes foot care educational interventions

Diabetes foot care education which includes written or verbal foot care instructions, group discussions on foot care, didactic foot care education, and counseling are directed to promote self-foot care practices and behaviors and prevent the incidence of DFU, or re-ulceration of a DFU. The results of the studies reviewed showed that diabetes foot care educational interventions improve patients self-foot care knowledge, practices and behaviors at short-term only, such improvement in foot care practices and behaviors are not sustained by diabetes patients at long term [9,11,18]. However, there is insufficient evidence of benefits supporting increased knowledge, and improved practices and behaviors led to reduced DFUs and re-ulceration. Although limited studies showed little evidence of benefits, [9,19] more robust evidence from well-designed RCTs are needed on this research subject because the available evidence are marked as high risks of bias, with methodological flaws raging from heterogeneous samples, under-powered samples, failure to address methods of randomizations, concealment, blinding and failure to reports characteristics of control and intervention groups. Educational interventions alone do not reduce the incidence of foot ulcers, re-ulcerations, and amputations in most diabetes patients especially those at the risk for foot ulcers [11-13,18].

Diabetes foot care complex interventions

Diabetes foot care complex integration which includes the integration of two or more preventive strategies such as foot care education, behavioral contracts, foot care assessment by podiatrist, verbal and written instruction, reminders on phone, encouraging therapeutic foot wears, and post card to reinforce self-foot care practices significantly improve diabetes patients self-foot care practices and behaviors. These interventions however yielded little evidence of benefits in preventing DFUs, re-ulceration and amputations [12,13]. The results of studies that evaluated the effectiveness of complex interventions showed a little or promising evidence of benefits. However, this study failed to report power analysis, and how randomization was performed. The results should therefore be viewed with caution and require confirmation in future research. Therefore, this study could not be considered high quality research evidence in assessing interventions for preventing DFUs and subsequent amputations. There is limited high-quality research evidence evaluating complex interventions [13].

There is little evidence of benefits that improved diabetes foot care, practices, and behaviors can sufficiently prevent DFUs at short-term in patients with diabetes mellitus. Results from studies reviewed showed that education intervention only have short term positive effects on influencing patients preventive foot care practices and behaviors, and failed to establish evidence of long term benefits such as preventing DFUs, re-ulceration, and amputation. These findings revealed that exclusive patients education is insufficient in achieving clinically relevant reductions in DFUs, re-ulceration and subsequent lower extremity amputations [12,11].

There are limited high-quality research evidence evaluating the effectiveness of foot care complex interventions in preventing DFUs and DFU re-ulceration [9,13]. The results showed a little or promising evidence of benefits. The research evaluating the effectiveness of complex foot care interventions for preventing DFUs, and DFU re-ulceration is promising and better design, randomized trials on this topic is needed to better inform clinicians and practitioners about effective preventative treatment [12,19].

Discussion

In sum, previous interventions have tested the role of education on

Table 2: Table of Findings from the Quantitative reviews.

Author	Outcomes	Findings	Implications
Liang R., Dai X., Zuojie, L, et al. (2012) [19]	Primary outcomes: diabetes knowledge, A1C levels, self-foot care behaviors. Secondary outcomes: Diabetic foot ulcers (DFUs), and amputations	No statistically significant difference between the intervention and control groups in diabetes knowledge score and self-foot care behavior assessment scores at baseline ($p>0.05$). However, participants in the intervention group scored higher on diabetes knowledge and foot care behaviors than those in the control group at one year ($p<0.05$) and two years ($p<0.05$). Additionally, there were zero amputations in the intervention group compared to two incidents of amputations in the control group.	Foot care program delivered by a nurse led multidisciplinary team can markedly improve foot care behaviors and diabetes outcomes to patients with diabetes at risk of developing DFUs, thereby reducing incidence of foot ulcer and amputation. There is evidence that a multidisciplinary managed foot care program can improve foot care behaviors and diabetes outcomes such as reducing incidence of DFUs and amputation among patients with diabetes at high risks for DFUs.
Dorresteijn J, Kriegsman D, Assendelf W, et al. (2012) [14]	Primary outcomes: DFUs, re-ulceration, and amputation. Secondary outcomes include process outcome such as such as diabetes foot care knowledge and foot care behaviors. Secondary outcomes also include clinical outcomes such as callus development, resolution of callus, fungal infection, number and duration of hospital admissions for diabetic foot	self-reported foot care knowledge and foot care behaviour seem to be positively influenced by education in the short term. However, only two sufficiently powered studies reported there is positive effect of patient education on primary end points. Only one RCT showed reduced incidence of DFUs and amputation after one-year follow-up. There is lack of sufficient or robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence.	There is lack of sufficient or robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence. Future RCTs should, the focus should be on comparing comprehensive educational interventions with usual care because usual care which comprises of basic and unstructured patient education on the diabetic foot, limited is unlikely to result in marked improvement of clinical outcome. The ultimate aim of foot care education for people with diabetes is to prevent foot ulceration and amputations. However, it seems that little evidence is available to support the effectiveness of patient education for the prevention of diabetic foot ulceration or amputations.
Lavery L, Lafointaine J, Higgins K, Lantoct D, Constantinides G (2012), et al. [17]	The primary outcome measured was the incidence of DFUs.	Participant in the STG were about 3.5 times more likely to develop an ulcer during the study period compared with participants treated in the SRI (odds ratio, 3.47; 95% confidence interval, 0.94–12.89). A shear-reducing insole may be more effective than traditional insoles to prevent DFUs in high-risk persons with diabetes.	There is evidence that an insole that reduces shear at the foot-insole interface can significantly reduce the risk of foot ulcerations in high-risk patients with diabetic neuropathy, deformity, and a history of foot ulcer than traditional insoles.
Navarro-Flores E, Noguerón, G, Cervera-Marín J, Labajos-Manzanares J (2015), et al. [10]	Primary outcomes diabetic foot self-foot care, diabetic self-foot examination Secondary outcomes Rates of amputations, foot care knowledge, quality of life.	There are not sufficient evidence indicating that educational intervention alone is sufficient to prevent diabetic foot complication. There is robust evidence that knowledge transfer alone is capable to achieving appropriate foot care behavioral practices	There is need for research whichcompare the effect of educational intervention to behavioral interventions and the effect of both on behavioral and clinical outcome. No sufficient evidence showed that patient teaching alone is sufficient in changing their foot care behaviors and reducing diabetic foot complications.
Netten J, Price P, Lavery L, Monteiro-Soares, (2016), et al. [29]	Primary outcomes were first diabetic foot ulcer and recurrent diabetic foot ulcer	Evidence did not support the effectiveness of complex foot care interventions in preventing first DFUs in patients at high risk for DFUs. Moreover, evidence did not support the effectiveness of a single educational intervention on the prevention of recurrent DFUs.	The best method of educating patients may not be available yet, further studies are needed to understand the most beneficial method for patient for desired outcome. More high-quality controlled studies are needed in these areas, in particular related to prevention of a first foot ulcer, patient education, self-management and surgical interventions, so to better inform clinicians and practitioners about effective preventative treatment.
Dorresteijn J, Kriegsman D, Valk G (2010), et al. [12]	Primary outcomes. Incidence of DFUs and the rates of amputations. Secondary outcomes callus development (e.g. presence of lesions, or a detailed description of the number, location or diameter of lesions); resolution of callus; number and duration of hospital admissions for diabetes related foot problems; foot care knowledge scores; patients' behavior assessment scores (e.g. washing, creaming, foot inspection, cutting toe nails, use of pumice stones, foot gymnastics); costs; adverse events. Trials were included if only secondary outcomes were reported	There was little evidence of long-term benefit found in preventing DFUs and amputation, because only one of these trials reported a significant effect on primary endpoints (amputation and foot ulceration incidence) and that study was at unclear or high risk of bias.	More well designed randomized trials that include sufficient samples of patients with diabetes at average risk of foot ulceration and evaluate the effect of complex interventions in primary prevention of DFUs. Future studies should randomized samples properly, with concealment allocation. Complex foot care intervention significantly impact foot care knowledge and practices, however, it showed little evidence of long term benefit in preventing DFU and amputation

Hoogeveen R, Dorresteijn J, Kriegsman D, Valk D (2015), et al. [13]	Primary outcomes. Incidence of DFUs, Rates of amputation Secondary outcomes callus development (e.g. presence of lesions, or a detailed description of the number, location or diameter of lesions); resolution of callus; number and duration of hospital admissions for diabetes related foot problems; foot care knowledge scores; patients' behavior assessment scores (e.g. washing, creaming, foot inspection, cutting toe nails, use of pumice stones, foot gymnastics); costs; adverse events. Trials were included even if only secondary outcomes were reported.	There was little evidence of long-term benefit found in preventing DFUs and amputation, because only one of these trials reported a significant effect on primary endpoints (amputation and foot ulceration incidence) and that study was at unclear or high risk of bias. Five RCTs reported amputation or DFUs incidence, or both, but only one of these was sufficiently powered. Two of these trials reported a significant effect on primary endpoints (amputation and foot ulceration incidence) and that study was at unclear or high risk of bias;	Evidence evaluating the effect complex interventions in preventing DFUs is still scarce, making it difficult for researchers to draw firm conclusions. A well designed randomized trials that include proper power analysis, more homogeneity of study characteristics and study reporting is needed. Future researchers should consider adequate reporting of baseline values and criteria for exclusion and inclusion, make efforts to reduce risk of bias, and poor reporting. Also, blinding of outcome assessors must be ensured
Norris S, Engelgau M, Narayan K (2001), et al. [22]	Primary outcomes. Knowledge, knowledge, attitude and self-care skills, lifestyle behaviors, psychological outcomes, quality of life, economic measures, glycemic control, and healthcare service utilization. Learning outcomes assessed are self-care scores, foot care knowledge scores, self-efficacy scores. Behavioral outcomes measured are: daily foot examination. Clinical outcomes: presence of DFUs and lesions, and risk for foot amputations.	Only one study reported a decrease in serious foot lesions at one year after an intervention consisting of group education. It is apparent that factors other than increasing knowledge are needed to achieve long-term behavioral change. There is lack of positive relationship between knowledge and self-management in diabetes.	Further research is needed to assess the effectiveness of self-management interventions on self-care behaviors such as sustained glycemic control, self-foot care skills, cardiovascular disease, and the quality of life. It is apparent that factors other than increasing knowledge are needed to achieve long-term behavioral change and that this may account for the lack of a consistent positive relationship between knowledge and self-management in diabetes
Bonner T, Foster M, Spear-Lanoix E, (2015), et al. [21]	Primary outcomes. Diabetes knowledge, self-foot care knowledge, self-care practices, and self-efficacy.	The lack of knowledge is recognized as a "contributing factor to why people with type 1 or type 2 diabetes do not undertake self-foot care practices.	Future research is needed to examine foot care knowledge and foot care practices of patients with diabetes' caregivers. Also the tensions between interventions tailored to individual needs and beliefs of a patient with the need for rigorous testing of standardized intervention
Boren S, Gunlock T, Schaefer J, Albright A, (2007).	Primary outcomes. Diabetes foot complications, callosities, nail disorders, feet amputations, and self-foot care. Secondary outcome. foot care knowledge, and foot care behaviors.	There was significant improvements in intervention participants' foot care knowledge and improvement in at least one foot care behavior such as feet washing, feet inspection, inspection of shoes, and adequate self-foot care practices.	Foot care educational intervention significantly impact foot care knowledge and practices, however, it showed little evidence of long term benefit in preventing DFU and amputation. Future RCTs should focus on diabetes risk reduction of diabetic neuropathy. Further studies are needed to test specific interventions to reduce the risks of diabetes complications.
Ahmad-Sharoni S, Minhat H, Zulkefli N, Baharom A (2015), et al.	Primary outcome: diabetes foot self-care practices (e.g. inspection, hygiene, appropriate socks and shoe, nail care, professional treatment) Secondary outcomes: diabetic foot ulcers, foot amputations, and foot disabilities.	There was significant improvement in self-foot care practices by combining educational intervention strategies compared to usual care. However, only one RCT showed improvement in both self-foot care practices and reduction in the incidence of DFUs.	There is scarcity of RCTs evaluating the impact of educational programs in improving self-foot care practices and reducing foot complications among older adults with diabetes mellitus. Combining two or more educational intervention strategies lead to significant improvement in self-foot care practices among older adults with diabetes. However, limited evidence exists that such interventions lead to reduction in diabetic foot complications.
Corbett CF (2003), [18].	Primary outcomes. Foot care knowledge (measured by foot care knowledge questionnaire), self-reported foot care practices (measured by foot care practices questionnaire) and self-efficacy (foot care self-efficacy questionnaire). Secondary outcome. Incidence of diabetic foot ulcers	A brief educational intervention, individualized according to patients' characteristics, improved participants' knowledge and reported foot care practices. At baseline, participants had many foot care knowledge but reported poor overall-foot care practices. There was very little change between the 6-week and 12-week assessments for participants in the control group, whereas participants in the intervention group improved significantly in knowledge (z=2.68, p.007), and reported foot self-care practices (z=3:00, P=.003). At 12 weeks, participants in the intervention group had significantly greater knowledge (z=2.27, P=.029) and improved self-care practices (z=2.73, P=0.007) compared with participants in the control group.	It is expected that patients will require repeated reinforcement on appropriate foot care practices to impact long term outcomes. Further research is needed on methods to best support foot health among patients with diabetes, as well as increasing the attention of healthcare professionals to diabetic foot health. Future research should consider a RCTs with multi-sites longitudinal design and long term follow-up period.

Lincoln NB, Radford KA, Game FL, Jeffcoate WJ, (2008), [19].	Primary outcome: Incidence of diabetic foot ulcers at 12 months. Secondary outcomes:Incidence of diabetic foot ulcers at 6 months, incidence of amputation, mood, quality of life, and protective foot care behaviors at 6 and 12 months. The primary outcome was measured by the occurrence of any new ulcers and was determined by medical and foot clinic records.	Specific or tailored educational intervention for DFUs patients, well-managed by podiatric clinics improve patients' self-foot care behaviors, but no evidence that such intervention prevent re-ulceration in patients with healed DFUs at six and 12 months	There is no robust evidence to rationalize the implementation educational intervention to prevent re-ulceration in patients with diabetes with recently healed DFUs. No indication of significant positive effect on the primary outcome even though the intervention appeared to be associated with improved foot care behavior in the intervention group. More research studies are needed to evidently establish the benefit patient education in improving the outcome of new ulceration in patients with recently healed DFUs.

improving knowledge, self-foot care practices, and health outcomes such as DFUs, re-ulceration, and amputations. Evidence demonstrates short-term effects in knowledge gained and self-care practices, but benefit in preventing long term health outcomes such as preventing DFUs [10]. More randomized trials that evaluate the effect of intensive comprehensive complex interventions are needed to better inform preventative treatment [20]. Preventing DFUs, re-ulceration, and amputations remains challenging because few interventions have been successful. There is no robust evidence to support the effectiveness of complex interventions in preventing DFUs and re-ulcerations in diabetes patients at high risk for DFUs, and diabetes patients with DFUs. There is a need for well-designed randomized trials that evaluate the effect of intensive comprehensive complex interventions [12-14,21]. The overall quality of intervention studies to prevent a foot ulcer in at-risk patients with diabetes should further improve, so that stronger recommendations for clinical practice. Further research is needed on methods to best support self-foot care practices among patients with diabetes, as well as to enhance foot assessment and interventions by healthcare professionals [22]. Research is needed to better understand how diabetes patients with DFUs perceive self-foot care practices and how such perceptions are associated with their daily foot-care practices because such an understanding may provide important insight into primary prevention strategies. Such a study should focus on targeted foot care needs of each patient [18].

It is apparent that other factors in addition to increasing knowledge of foot care or teaching diabetes patients about foot care are required to achieve long-term behavioral change and the robust benefits of foot care practices [21]. Patients' teaching or educational intervention alone may not be successful because most patients do not follow foot care recommendations and advice from health care professionals [23-29]. Evidence indicated patients did not engage in advised preventive foot care practices. One study suggested that patients who reported "knowing enough" about specific foot self-care practices did not actually engage in the advised practice and health perceptions and beliefs are recognized as important determinants of patients' behaviors towards diabetes foot care practices because individuals who perceive foot care practices as important, are more likely to engage in foot self-care practices than individuals who perceived it as less important. Therefore, research is needed to better understand how diabetes patients perceive foot care practices and how such perceptions are associated with their daily foot-care practices because such an understanding may provide important insight into primary prevention strategies [27]. Findings from such studies may provide support for the development of future RCTs interventions aimed at promoting diabetic self-foot care practices and preventing DFUs, and re-ulceration in patients with diabetes.

Three, out of the four reviewed RCTs are precluded with methodological flaws ranging from under-powered samples, failure to address methods of randomization, concealment, and failure to report characteristics of control and intervention groups, and clearly describe the differences between the control and intervention group. Three (n=3) out the nine systematic reviews used the Cochrane Collaboration tools for assessing risks of bias in their included studies, while the remaining six reviews (n=6) did not identify tools used in assessing the risk of bias in their included studies. Only one RCT addressed the randomization of sequence and allocation of concealment [18]. Thus, there is limited high-quality research evidence evaluating complex interventions for preventing diabetic foot ulceration [12,13]. However, this study failed to report power analysis, and how randomization was performed. The results should therefore be viewed with caution and require confirmation in future research. Therefore, this study could not be considered high quality research evidence in assessing interventions for preventing DFUs and subsequent amputations.

Key limitations of the current literature review should be discussed. First, only one reviewer was included in this study, thus, the observations and suggestions presented are based only on the researcher's findings. The heterogeneity of the RCT studies made it impossible to create a funnel plot to evaluate the presence of publication bias. Included studies used different tools to assess foot care knowledge and self-foot care practices. Therefore, it was not feasible to evaluate the clinical relevance of the statistically significant improvements reported.

Conclusion

There is evidence that foot care education improve foot care knowledge, practices, and behaviors. There is promising evidence that foot care complex interventions can reduce DFUs. However, there is lack of sufficient evidence to supports the effectiveness and benefits of foot care education and complex foot care intervention that aim to prevent DFU, DFU re-ulceration, and lower extremity amputations. Efforts to increase diabetes foot care education aimed at improving foot care knowledge, practices, and behaviors may not be sufficient in achieving primary and secondary prevention of DFUs in patients with diabetes mellitus. Future research should consider a RCTs with multi-sites longitudinal design and long term follow-up period. Moreover, future RCTs should focus on designing individualized patient-centered interventions and accounts for powered samples, methods of randomization and concealment and proper reporting of sample characteristics. There is gap in research on the best foot care practices intervention for primary and prevention of DFUs. It is imperative to design more high quality RCTs, to provide stronger recommendations to clinicians and healthcare practitioners on the best clinical and educational interventions to prevent DFUs, DFU re-ulceration and subsequent lower extremity amputations.

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Authorship

DO initially designed the study and synthesized the data (2016), and wrote the article. DO and JP collected all data. DO, JP, PE, GO, and JP carried out the analyses. DO and JP developed and wrote the study protocol. All authors read, corrected and approved of the article.

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